IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JANSSEN PRODUCTS, L.P. et al., Plaintiffs, v. EVER VALINJECT GMBH, et al., Defendants.	Case No. 24 CV 07319 Honorable Sunil R. Harjani

MEMORANDUM OPINION AND ORDER

Plaintiff Pharma Mar, S.A. holds title to United States Patent No. 8,895,557 (the '557 Patent), which covers compositions comprising ET-743 (also known as trabectedin) and a disaccharide to reduce the impurities formed during storage, as well as methods to prepare such compositions. Plaintiff Janssen Products, L.P. holds the exclusive license to the '557 Patent and sells Yondelis®, a drug used to treat rare forms of soft-tissue cancer with ET-743 as its active ingredient. Plaintiffs bring this action against Defendants EVER Valinject GmbH, Nexus Pharmaceuticals, LLC, Shanghai Haoyuan Chemexpress Co., Ltd., and Ruyuan HEC Pharm Co., Ltd. for infringement under the doctrine of equivalents and asks for declaratory judgment that Defendants may not manufacture or sell its proposed generic version of Yondelis®. EVER and Nexus counterclaim that the proposed product is non-infringing and that the '557 Patent is invalid.

On October 28, 2025, the Court heard argument on the parties' claim construction briefs. The disputed terms can be found in three of the claims in the '557 Patent:

> 1. A lyophilised anti-tumor composition comprising a single active anti-tumor compound and a disaccharide selected from sucrose, lactose and a combination thereof, wherein the anti-tumor compound is ET-743 and wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701,

> such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C. for 3 months.
>
> 17. A method of reducing the formation of ET-701 in a composition of ET-743, comprising freeze-drying a bulk solution that comprises ET-743 and a disaccharide to yield a composition according to claim 1 wherein said disaccharide is selected from sucrose, lactose and a combination thereof.
>
> 22. A lyophilized anti-tumor composition comprising a single active anti-tumor compound and a disaccharide selected from sucrose, lactose and a combination thereof, wherein the anti-tumor compound is ET-743 and wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 25°C. for 3 months.

A0027–28.[1] For the reasons stated below, the Court adopts the constructions identified at the end of this Order.

Legal Standard

Before a court can determine whether an accused product infringed a patent, it must first determine the meaning and scope of the patent claims asserted to be infringed. *Markman v. Westview Instr., Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Claim construction based solely on intrinsic evidence is a question of law. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). It begins with the claims of a patent, which define the invention, then moves to the specification as "the single best guide to the meaning of a disputed term," before considering the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–1317 (Fed. Cir. 2005). Claim terms "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application" after

[1] "A###" citations are to the Joint Appendix in Support of Claim Construction Briefing. [231]. Also, a prior disputed term was resolved at the claim construction hearing by stipulation.

reading the entire patent. *Id.* at 1312–13, 1321 (citation omitted). However, the patentee's demonstrated use of a term, as reflected in the intrinsic evidence, controls over its ordinary meaning. *See Markman*, 52 F.3d at 980 ("[A] patentee is free to be his own lexicographer" so long as "any special definition given to a word [is] clearly defined in the specification"); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2003) ("This court also considers the prosecution history to determine whether the applicant clearly and unambiguously disclaimed or disavowed any interpretation during prosecution in order to obtain claim allowance." (cleaned up)). The guiding principle is to read claims in context of entire patent, so that the construction "stays true to the claim language" while "most naturally align[ing] with the patent's description of the invention." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998); *see Phillips*, 415 F.3d at 1315 (claims are "part of 'a fully integrated written instrument'" (citing *Markman*, 52 F.3d at 978)). Extrinsic evidence may be used to understand the patent and assist in its construction but "not for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981.

Claim indefiniteness is also a question of law. A patent "must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Nautilus, Inc. v. Biosig Instr., Inc.*, 572 U.S. 898, 909 (2014) (cleaned up). Although absolute precision is unattainable, a patent's claims, "viewed in light of the specification and prosecution history," must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Id.* at 910. "Words of degree are not inherently indefinite, but the court must determine whether the patent provides some standard for measuring that degree." *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1284 (Fed. Cir. 2023) (cleaned up). Additionally, when a claim limitation is defined in "purely functional terms," i.e., "by what it does rather than what it is," the claim's definiteness

is "highly dependent on context." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1255 (Fed. Cir. 2008) (citation omitted); *Biosig Instr., Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015). "Any fact critical to a holding on indefiniteness, moreover, must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003).

Discussion

With the above principles in mind, the Court turns to each of the disputed terms.

Disputed term 1: "wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701"

The first term at issue is found in claims 1 and 22 identifying a lyophilized (freeze-dried) anti-tumor composition comprising ET-743 and a disaccharide that is either sucrose, lactose, or a combination thereof.[2] The claimed invention is limited to such a composition "wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701." Plaintiffs argue that a person of ordinary skill in the art (POSA) would understand the plain and ordinary meaning of the term to communicate that the disaccharide is inhibiting the conversion of ET-743 into ET-701 to obtain a composition that "comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C. [or 25°C.] for 3 months" as claimed.[3] Defendants request an alternative construction to address two points. First, Defendants argue that the word "inhibit"

[2] The only difference between claims 1 and 22 is the storage temperature: the composition in claim 1 is stored at 5°C. for 3 months, and the composition in claim 22 is stored at 25°C. for 3 months.

[3] Plaintiffs submitted an expert declaration that defines a POSA in this case as a person who has "a Bachelor of Science or Master of Science degree in pharmaceutics, chemistry, chemical engineering, or a related field, with 1–2 years of industry or related experience in drug formulation and/or drug delivery." [238-1] ¶ 34. Defendants offered no alternative definition of a POSA, do not contest Plaintiff's definition, and even seem to adopt the definition in their reply brief by relying on statements by Plaintiffs' expert about what a POSA would understand. *See* [252] at 3. Therefore, the Court adopts this definition. *See Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1376–78 (Fed. Cir. 2022) (applying one party's definition of a POSA after opposing party "chose not to contest, and even seemed to adopt," the definition).

means that the claimed disaccharide is preventing any conversion at all of ET-743 into ET-701, and they request the Court adopt the word "preclude" to highlight this point. Second, they argue that the claimed disaccharide is the only inactive ingredient (excipient) that inhibits the conversion of ET-743 into ET-701. Thus, Defendants propose as a construction: "an amount of disaccharide to preclude conversion of ET-743 into ET-701."

To understand the term "inhibit," the Court starts with "the words of the claims themselves." *Phillips v. AWH Corp.*, 415 F.3d at 1312 (citation omitted). The claims say that the disaccharide is sufficiently present to "inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C. [or 25°C.] for 3 months." The plain language definitely establishes a limitation on the amount of ET-701 after three months, but it does not establish a non-zero cap during the three months. Thus, "inhibit" cannot mean "preclude." In addition, Defendants' proposed construction would read in a limitation on fluctuations prior to three months—specifically, it would require a composition to start at an ET-701 level that is less than 2% and never exceeds that starting level, with no new conversions to ET-701. However, the '557 Patent's specification provides "highly instructive" context that teaches otherwise. *Id.* at 1314. It provides tables that show the results of comparative studies between "conventional" ET-743 compositions without a disaccharide and embodiments of the claimed compositions on ET-701 formation when stored at 5°C and 25°C. Tables XIV and XV show increases in the amount of ET-701 in claimed compositions (labeled with the prefix "ET-NF" in the tables) from the time of lyophilization (t=0) and three months, though the amounts remain below 2%. Table IV shows ET-701 in claimed compositions (labeled as "sucrose," "lactose," and "ET-poly80sacc") rising after one month but staying below 2%.

TABLE XIV

	ET-701 (%)				
	Reference 1	Reference 2	Reference 3	ET-NF A	ET-NF B
t = 0	0.70	0.84	0.53		0.11
1 month	2.56	3.09	1.73		0.12
2 month	3.45	3.54	2.69	0.12	0.13
3 month	4.61	5.04	4.28	0.13	0.13

	ET-701 (%)			
	ET-NF C	ET-NF D	ET-NF E	ET-NF F
t = 0	0.15	0.16	0.15	0.11
1 month	0.12	0.12	0.14	0.11
2 month	0.16	0.14	0.15	0.12
3 month	0.16	0.15	0.15	0.12

TABLE XV

	ET-701 (%)				
	Reference 1	Reference 2	Reference 3	ET-NF A	ET-NF B
t = 0	0.70	0.84	0.53	0.09	0.11
15 days	7.99	8.20	4.22	0.14	0.12
1 month	10.56	14.18	6.86	0.11	0.12
2 month				0.15	0.16
3 month				0.17	0.17

	ET-701 (%)			
	ET-NF C	ET-NF D	ET-NF E	ET-NF F
t = 0	0.15	0.16	0.15	0.11
15 days	0.18	0.17	0.16	0.13
1 month		0.18	0.18	
2 month	0.18	0.19	0.24	0.15
3 month	0.22	0.23	0.24	0.18

TABLE IV

	ET-701 (%)			
	Reference	Sucrose	Lactose	ET-poly80sacc
t = 0	0.188	0.066	0.060	0.050
1 month	0.533	0.063	0.076	0.060
3 months	0.890	0.057	0.054	0.050
6 months	1.732	0.050	0.062	0.050
9 months	3.225	0.050	0.050	0.050

These minor increases in ET-701 still accomplish the goal of the invention to reduce levels of ET-701 formulation in the claimed compositions compared to the levels found in conventional compositions, which are represented by the tables' reference compositions. Considering this context, "inhibit" in claims 1 and 22 cannot mean that there is no new conversion of ET-743 into ET-701 at all. Nor do the tables show that ET-701 is entirely eliminated by the invention. A POSA is assumed to have read the entire patent, so they would have reasonably considered these tables when reading claim 1 and understood that some ET-701 conversion may take place. *See Phillips*, 415 F.3d at 1313.

Part of Defendants' justification for defining "inhibit" as "preclude" is to give it a different meaning from the word "reduce," which is found in claim 17. Defendants cite *Toro Co. v. White Consolidated Industries, Inc.* for the presumption that words and phrases in separate claims have different meanings and scope. 199 F.3d 1295, 1302 (Fed. Cir. 1999). However, *Toro* explains that different meanings are only needed when the absence of such difference would make a claim

superfluous. *Id.* Claims 1 and 22 are composition claims while claim 17 is a method claim, so they do not conflict. Regardless, "reduce" in the '557 Patent is used simply to describe one purpose that the composition in claims 1 and 22 accomplishes. The specification repeatedly refers to conventional ET-743 compositions that do not contain sucrose or lactose and uses them as references in the cited studies to show that they have more ET-701 formation over time than the claimed compositions. *See, e.g.*, A0021 ("[T]he main degradation product of the reference formulation, ET-701, was dramatically reduced when ET-743 was formulated in the presence of sucrose or lactose."); *id.* ("Embodiments of formulations according to this invention have impurity content that is significantly reduced with respect to that of conventional formulations. Presence of ET-701 is accordingly reduced."). In other words, the specification makes clear that the disaccharide in the claimed composition reduces the amount of ET-701 as compared to a conventional composition without a claimed disaccharide. That use of "reduce" is consistent with the function of the claimed composition "inhibit[ing]" conversion of the ET-743 into ET-701.

The other half of Defendants' request is for a construction that limits claims 1 and 22 to compositions of ET-743 and sugar, lactose, or a combination thereof in which the sugar, lactose, or combination is the only ingredient that is inhibiting conversion of ET-743 into ET-701. However, their proposed construction does not teach this limitation. Rather, their request equates to a construction as follows: "wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C. [or 25°C.] for 3 months *without any other ingredient in the composition inhibiting conversion of the ET-743 into ET-701*." Claims 1 and 22 do not make any such restriction. Nor does the specification "reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Philips*, 5 F.3d at 1316. The prosecution history

supports the limitation that a disaccharide performing the described inhibiting function must be sucrose, lactose, or a combination thereof, and must be present in sufficient amounts to inhibit the conversion, but that does not explicitly or implicitly require that no other excipient be included in the composition. It is certainly the case that the claimed disaccharide is playing a primary role in "dramatically" reducing the ET-701 formation, but there is no evidence that the claimed compositions—or conventional compositions, for that matter—exclude some other excipient that reduces ET-701 formation to a minor degree. Reading this limitation into the claims would not "stay[] true to the claim language" and is not required for the claims to naturally align with the description of the invention. *See Renishaw*, 158 F.3d at 1250. A POSA would understand the claims' limitation to be tied to the claimed disaccharide's inhibiting function and not the inhibiting function of other excipients, if any.

Alternatively, Defendants argue that claims 1 and 22 are indefinite because a POSA cannot reasonably know whether other excipients that inhibit ET-701 conversion can be part of the claimed composition. They argue that for an ET-743 composition with a claimed disaccharide and another inhibiting excipient, it is not possible to know which excipient is performing the inhibitory function in an ET-743 composition and, therefore, whether there is a "sufficient amount" of the disaccharide to inhibit ET-701 conversion. However, the words of degree "sufficient amount" are not inherently indefinite. *Ironburg Inventions Ltd.*, 64 F.4th at 1284. Defendants provide no factual support for the assertion that it is impossible to attribute the inhibiting function to various excipients in a given composition, including the disaccharide to determine whether it is in a sufficient amount. Without such evidence, the claims provide an acceptable standard of measuring the amount of disaccharide against the specific attributes that the overall composition must achieve and is "precise enough to afford clear notice of what is claimed." *Nautilus*, 572 U.S. at 909.

Defendants fail to show by clear and convincing evidence facts that are critical to a holding on indefiniteness. *Intel Corp.*, 319 F.3d at 1366. At this stage, it is sufficiently clear from the plain and ordinary meaning that the composition contains sucrose, lactose, or a combination thereof in an amount sufficient to have an effect on ET-701 conversion, and that effect must result in an ET-743 composition comprising "less than 2% ET-701 after storage of the ET-743 composition at 5°C. [or 25°C.] for 3 months."

"reducing the formation of ET-701"

The next disputed term is "reducing the formation of ET-701" in claim 17. Plaintiffs' position is that the term is a non-limiting preamble that merely states a purpose of the invention. Defendants argue that that this purpose must be limiting because its absence would leave the claim without meaning.

Whether a preamble is limiting or not depends on "what the inventors actually invented and intended to encompass by the claim." *In re Xencor, Inc.*, 130 F.4th 1350, 1356 (Fed. Cir. 2025) (citation omitted). It is a case-by-case determination based on "the claim as a whole and the invention described in the patent." *Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358 (Fed. Cir. 2010) (citation omitted). Generally, "the preamble does not limit the claims." *Id.* (citation omitted). If the claim "defines a structurally complete invention" without the preamble language, then the language is not limiting. *Xencor*, 130 F.4th at 1357. However, if the preamble is "necessary to give life, meaning, and vitality" to the claim, it limits the scope of the claim. *Id.* (citation omitted). In other words, the preamble is limiting if it is not "merely duplicative of the limitations in the body of the claim" or "was not clearly added to overcome a prior art rejection." *Am. Med. Sys.*, 618 F.3d at 1359 (cleaned up).

Defendants deem the preamble as limiting because it gives "life, meaning, and vitality" to the claim. In *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, the Federal Circuit

affirmed that the preamble in a claim for "a method of growing and isolating [a virus], which comprises inoculating the virus on [simian cells]" was limiting because it embodied the "essence of the invention[,] without which performance of the recited steps is nothing but an academic exercise. 320 F.3d 1339, 1345 (Fed. Cir. 2003). In *Jansen v. Rexall Sundown, Inc.*, the preamble of "treating or preventing macrocytic-megaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B12 deficiency" was a limiting part of the claim for administering daily doses of folic acid and vitamin B12 because it was needed to give meaning to the rest of the claim. 342 F.3d 1329, 1333–34 (Fed. Cir. 2003). The language had been added to overcome prior art, so "administering the claimed vitamins in the claimed doses for some purpose other than treating or preventing macrocytic-megaloblastic anemia [was] not practicing the claimed method." *Id.* at 1334. In *Eli Lilly & Co. v. Teva Pharmaceuticals International GmbH*, the challenged patents directed to methods of "reducing incidence of or treating at least one vasomotor symptom in an individual" and "treating headache in an individual," which comprised of administering to the individual an "effective amount of" the claimed antibody. 8 F.4th 1331, 1335–36 (Fed. Cir. 2021). Relying on *Boehringer Ingelheim* and *Jansen*, the Federal Circuit affirmed that these terms were limiting preambles because they were the only portions of their respective claims that "embodied the essence of the claimed invention—methods for treating vasomotor symptoms." *Id.* at 1342. The preambles were also necessary to understand the rest of the claims: they enabled a POSA to understand that an "effective amount" of the antibody was enough to treat or prevent a headache or migraine, and they taught that the individual receiving the antibodies was the same individual needing treatment for a headache or migraine. *Id.* at 1342–43. Therefore, the preamble gave "life and meaning to the method step of each claim." *Id.* at 1343.

Comparing claim 17's preamble to the preambles in these cases, the removal of the preamble language would not reduce the claim down to an "academic exercise" as in *Boehringer Ingelheim*. Without the preamble language, claim 17 still teaches "freeze-drying a bulk solution that comprises ET-743 and a disaccharide to yield a composition according to claim 1," meaning that composition has the disaccharide "present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C. for 3 months." By incorporating claim 1, claim 17 instructs a POSA that this is a method involving the inhibition of ET-701 conversion, which results in a reduction of ET-701 formation. *Cf. ABS Glob., Inc. v. Inguran, LLC*, 914 F.3d 1054, 1069 (7th Cir. 2019) ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers." (quoting 35 U.S.C. § 112(d))). Thus, the claim still defines the invention. *Phillips*, 415 F.3d at 1312.

The preamble is similar to that in *TomTom, Inc. v. Adolph*, 790 F.3d 1315 (Fed. Cir. 2015), in which the Federal Circuit found that the district court erred in holding part of the claim's preamble limiting. The preamble began with "a method for generating and updating data," but the body of the claim also stated "generating and storing section data in the storage device" and "said section data file being continuously supplemented and/or updated with section data newly generated." *Id.* at 1318. The Federal Circuit found that the language did not provide an antecedent basis for any of the claims and simply stated a purpose or intended use. *Id.* at 1323–24. In like manner, the "reducing" language in claim 17 merely states a purpose served by making the claimed composition according to the method. Claim 17 "employs the standard pattern of such language: the words 'a method for a purpose or intended use comprising,' followed by the body of the claim, in which the claim limitations describing the invention are recited." *Id.* at 1324. It states the

purpose of reducing ET-701 formation, and the body requires a composition in which the disaccharide inhibits ET-701 formation. In full context of the claim, the preamble "is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim." *Am. Med. Sys.*, 618 F.3d at 1359.

Unlike *Jansen*, the preamble was not added to overcome prior art such that its removal would render the claim invalid. The prosecution history shows that claim 17 has had the term since the beginning and only undergone amendment to clarify that it incorporated the claimed compositions. A0085 (originally listed as claim 18, for "freeze-drying a bulk solution that comprises ET-743 and a disaccharide"); A0136–37 (adding to claim that it yields a composition according to claim 11, which is a "composition according to claim 1"); A3361 (cancelling claim 11 and amending original claim 18 to correct its dependency to claim 1). The United States Patent & Trademark Office (PTO) recognized claim 17 and other method claims as "drawn to a method of making an ET-743 formulation" and reiterated this purpose throughout prosecution. A0127, A0329, A4077, A4258–59. Its fate has always been tied to the patentability of the claimed compositions, not the preamble language. *See, e.g.*, A4077–79 (rejecting claim 17 with other claims based on issues with the composition of ET-743 and a disaccharide); A4257–59 (allowing claim 17 after amendment specifying that it makes a composition of ET-743 and a disaccharide "wherein the disaccharide is selected from sucrose, lactose and a combination thereof"). Similarly, the rest of its language has not rested on the preamble to define the method, unlike the claims in *Eli Lilly* that required the preamble to understand who needed treatment or how much treatment to give. 8 F.4th at 1342–43. The court in *Eli Lilly* found that the preamble language vital to the method claim, but as the '557 Patent's prosecution history confirms, the vitality of claim 17 rests with a method for preparing the composition identified in claim 1. *See id.* at 1342.

As a final effort to prove that the preamble must be a limitation, Defendants briefly argue that claim 17 recites an identical method to claim 16 if their preambles are not limiting. Claim 16 is not before the Court for construction, but a claim must be read in context of the entire patent. *Renishaw*, 158 F.3d at 1250. Assuming claim 16's preamble is also not limiting, *see Am. Med. Sys.*, 618 F.3d at 1358, there is still a distinction between the claims. Claim 16 covers "[a] method of making a lyophilised composition of ET-743 according to claim 1, comprising freeze-drying a bulk solution that comprises ET-743 and a disaccharide wherein said disaccharide is selected from sucrose, lactose and a combination thereof." Without the preamble, the claimed invention is the method of freeze-drying a bulk solution that comprises ET-743 and a disaccharide. That is distinct from the invention in claim 17, which is the method of freeze-drying a bulk solution of ET-743 and a disaccharide "to yield a composition according to claim 1," meaning that there is enough disaccharide to inhibit ET-701 conversion and to result in less than 2% ET-701 after storage at 5°C. for three months. Two claims can cover the same subject matter "to define the metes and bounds of the invention in a variety of different ways." *Tandon Corp. v. U.S. Int'l Trade Comm'n*, 831 F.2d 1017, 1023 (Fed. Cir. 1987) (citation omitted). The fact that both cover the subject matter of creating the compositions is insufficient on its own to show they are the same. After reading the specification, a POSA would expect some overlap between the method claims, as the summary of invention describes five methods, but there are only four method claims. Additionally, the distinction between the two claims is supported by the prosecution history. In the PTO's notice of allowability, the patent examiners acknowledged the patentability of both claims 16 and 17 (formerly claims 17 and 18). A4257–59. They wrote that the composition of "lyophilized ET-743 and a disaccharide selected from the group consisting of lactose or sucrose is not anticipated in the prior art"—claim 16. A4258. "Moreover, the . . . prior art fail[s] to teach, suggest, or make obvious

the unexpected stability of lyophilized ET-743, coupled with the inhibition of generating . . . ET-701 when formulated with the disaccharides sucrose or lactose and stored at 5°C or 25°C for 3 months"—claim 17. A4258–59. Though the Court does not construe claim 16 absent any dispute raised by the parties, it finds that claim 16's language does not compel a limiting construction of claim 17's preamble language.

The preamble language is neither necessary for a POSA to understand that the method in claim 17 reduces ET-701 formation in an ET-743 composition containing a claimed disaccharide, nor to overcome prior art, nor to give meaning to the rest of claim 17's language, nor to differentiate claim 17 from claim 16. Rather, the preamble is merely a "statement[] of effect" that is non-limiting and requires no construction. Thus, the Court does not construe it and does not reach Defendants' argument on indefiniteness.[4]

"a single active anti-tumor compound"

The final term is the phrase "a single active anti-tumor compound" in claims 1 and 22. Both parties agree that the term should have its ordinary and plain meaning.

Despite this agreement, Defendants take issue with the word "active." They posit that an impurity that forms in an ET-743 composition and provides an anti-tumor effect could be called a second "active anti-tumor compound," which fall outside the scope of the claims. They propose an alternative meaning of "a single compound providing anti-tumor properties," but this definition is susceptible to the same concern—an impurity that forms in the composition and provides an

[4] For the same reason, the Court rejects Defendants' proposed construction of the term as "lessening the formation of ET-701 relative to the same formulation without the claimed disaccharides." As explained above, the use of the word "reduce" in the specification is understood as comparing the amounts of ET-701 formation between the claimed compositions in claims 1 and 22 and a composition without a claimed disaccharide. This is already consistent with the plain and ordinary meaning of claim 1 and not a limiting purpose in claim 17.

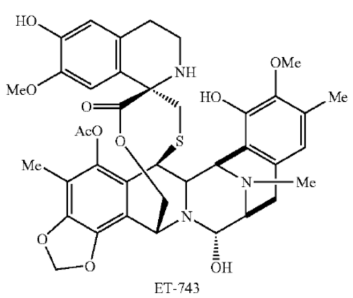
anti-tumor effect could be called a second "compound providing anti-tumor properties" and arguably fall outside the claim's scope in the same way.

This dispute was raised in *Janssen Products, L.P. v. eVenus Pharmaceuticals Laboratories Inc.*, 2022 WL 1044970 (D.N.J. Apr. 7, 2022), in which the court construed terms in the '557 Patent for another patent infringement suit that Plaintiffs brought against different defendants. The parties disputed the same term, "a single active anti-tumor compound," and defendants there similarly pushed for the alternative definition of "single compound possessing anti-tumor properties." *Id.* at *3. The court recognized that the "crux of the parties' dispute" was whether impurities could become a second active ingredient, and it ruled that this was not an issue of claim construction but rather one of infringement, better saved for a later stage. *Id.* at *7–8. This Court reaches the same conclusion. Generally, claim terms are given their ordinary and custom meaning absent evidence that the patentee used its own definition or disavowed the ordinary meaning. *3M Innovative Props.*, 350 F.3d at 1370–71. The parties raise no contention about the other words in the term, and they agree that "active" refers to a chemical compound that provides a therapeutic effect, which, here, is an anti-tumor effect. [238] at 19; [252] at 14–15. That is all the "specificity and precision [that] is warranted by the language of the claim and the evidence bearing on the proper construction," so additional construction would be improper. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998). Defendants' contention is not a question as to the definition of "active" but rather a question of whether an impurity in an ET-743 composition *can be* active. Because that inquiry goes to infringement rather than claim scope, the Court does not resolve it now. *Eon Corp. IP Holdings v. Silver Spring Network*, 815 F.3d 1314, 1318–19 (Fed. Cir. 2016); *see, e.g.*, *Lazare Kaplan Int'l, Inc. v. Photoscribe Techs., Inc.*, 628 F.3d 1359, 1375–76 (Fed. Cir. 2010) (denying argument that the district court failed to construe a disputed term beyond the parties' stipulation

because "the parties' dispute concern[ed] factual questions relating to the test for infringement and not the legal inquiry of the appropriate scope of the" term). Therefore, "a single active anti-tumor compound" has its plain and ordinary meaning and requires no further construction.

Conclusion

For the reasons stated above, the Court will construe the disputed and stipulated terms of the patent in suit in accordance with the table below.

TERM	COURT'S CONSTRUCTION
"ET-743" (stipulated)	"a compound with the following structure:  ET-743
"wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701"	"wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701" (i.e., plain meaning)
"reducing the formation of ET-701"	non-limiting preamble, no construction necessary
"a single active anti-tumor compound"	"a single active anti-tumor compound" (i.e., plain meaning)

SO ORDERED.

Dated: November 10, 2025

Sunil R. Harjani
United States District Judge